IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Amar Lulla, *et al.*	§	
		§	Group Art Unit: 1618
Serial No.:	10/574,135	§	
		§	Examiner: Nissa M. Westerberg
Filed:	October 18, 2006	§	
		§	Confirmation No.: 8688
For:	PHARMACEUTICAL FORMULATION WITH IMPROVED STABILITY	§	

Commissioner for Patents
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CERTIFICATE OF EFS-WEB FILING

Pursuant to 37 CFR. §1.8, I hereby certify that this correspondence is being electronically submitted to the U.S. Patent and Trademark Office website, www.uspto.gov, on 7/25/2008

Edith Shek

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RESPONSE TO RESTRICTION REQUIREMENT

Sir:

Applicants respectfully traverse the species election requirement set forth in the Office Action dated June 25, 2008. First, Applicants respectfully submit that the Examiner has not identified species as set forth in claims 7-10, but rather individual chemical compounds, namely alendronate sodium trihydrate, etidronate disodium and risedronate sodium monohydrate. More specifically, Applicants respectfully submit that the Examiner's alleged species do not actually represent species but instead represent individual compounds within a species because each of the Examiner's alleged species can contain only one member. In contrast to individual compounds, a species is a class of individuals having some common characteristic(s) or attribute(s). *See e.g.*, *Merriam Webster's Collegiate Dictionary* 10th edition.

Second, the Examiner has failed to establish that the alleged species lack a common special technical feature establishing unity of invention. Independent claim 1 recites "an oral formulation which includes an intragranular phase comprising a bisphosphonic acid derivative and at least one carbohydrate alcohol, together with an aqueous binder." The combination as recited in independent claim 1 serves as the special technical feature that is generic to the alleged species identified in claims 7-10 depending from claim 1. Applicants note that the Examiner has not cited any prior art as teaching the special technical feature, and thus the special technical feature supports unity as established during the International Phase.

Third, the Examiner's rationale in paragraph 3 of the office action is insufficient to show that the species lack a common technical feature. The fact that the various compounds encompassed by the claim "having varying attributes … and various compounds are presented" is irrelevant to unity. Various compounds are allowed by way of generic claim limitations, and the Examiner's statements lend support to our explanation above that the alleged species are not species at all, but rather individual compounds. Likewise, the Examiner's assertion that "[t]here is nothing of record to show them to be obvious variants" is not an appropriate standard of review in a PCT unity analysis. Such statement appears to indicate that the Examiner is impermissibly applying U.S. restriction practice standards to this national stage PCT application.

Despite the forgoing and in an effort to substantively advance prosecution, Applicants elect with traverse the species of alendronic acid as listed in claim 3. At least claims 1, 3, and 14 encompass (e.g., are generic to) the alendronic acid species. Of course, if certain claims encompassing the elected species are found patentable, then other claims depending from such patentable claims (for example, various of claims 2, 4-8, 11-13, 15-35) would likewise be allowable for similar reasons.